IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

SCOTT WARNER, et al.,

Plaintiffs,

v.

STRYKER CORPORATION, a Michigan corporation and STRYKER SALES CORPORATION, a Michigan corporation, et al.,

Defendants.

Civ. No. 08-6368-AA
OPINION AND ORDER

AIKEN, Chief Judge:

Plaintiff Scott Warner filed suit alleging products liability and negligence after a medical device known as a "pain pump" was used to administer local anesthetics into Warner's shoulder joint after arthroscopic surgery. Warner seeks economic, non-economic, and punitive damages. Defendants Stryker Corporation and Stryker Sales Corporation (collectively Stryker) were the alleged manufacturer and distributer of the pain pump.

Stryker now moves for summary judgment on Warner's claims.

Stryker argues that it did not know and could not have known of any risk associated with pain pump use in the joint space prior to Warner's surgery, and therefore it had no duty to warn of such risk. Stryker also argues that Warner cannot prove that Stryker's alleged failure to warn of such risk caused Warner's injuries, or that Warner is entitled to punitive damages. The motion is denied.

BACKGROUND

Pain pumps are medical devices used to administer prescribed amounts of pain medication directly to a certain area of the body. The marketing, labeling, and sale of pain pumps are regulated by the Food and Drug Administration (FDA). The FDA classifies medical devices into three types: Class I, Class II, and Class III. 21 U.S.C. § 360c. Stryker's pain pumps are Class II devices.

Prior to marketing a new Class II medical device, a manufacturer must obtain Premarket Approval (PMA) for the device, unless an exception applies. See id. §§ 360c, 360e. As pertinent to this case, the "substantial equivalent" exception permits the marketing of a new Class II device through the premarket notification process, commonly known as the "510(k)" notification process. Id. §§ 360c(f), 360(k). "Under the 510(k) process, if the Class II device is deemed 'substantially equivalent' to a pre-existing device with prior clearance, 'it can be marketed without further regulatory analysis.'" PhotoMedex, Inc. v. Irwin,

601 F.3d 919, 925 (9th Cir. 2010) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 478 (1996)). "In other words, that device receives '510(k) clearance' and can be put on the market." Id. The 510(k) notification process is much less rigorous than the PMA process and requires no additional testing of the device. Id.; Medtronic, 518 U.S. at 478-79.

In 1999, Stryker began distributing pain pumps manufactured by McKinley Medical, LLC, and in 2000, Stryker acquired the product. In 2002, Stryker introduced a second version of the pain pump which included a programmable computer to regulate the dosage and administration of medication. As with other brands of pain pumps, Stryker's pain pumps are prescription devices sold to health care providers and prescribed by licensed physicians.

The parties agree that at all relevant times, Stryker's pain pumps were cleared through the 510(k) notification process for general surgery applications and "interoperative" use. Hoffman Decl. at 2; Young Decl. Ex. 19 (filed under seal). Notably, McKinley Medical and Stryker had sought 510(k) clearance to market pain pumps for the specific indication of orthopedic use and/or use in the joint cavity. See, e.g., Young Decl. Exs. 5 (filed under seal), 6 (Petty Dep. at 17), 10 (Petty Dep. at 198-99). Ultimately, the FDA determined that a substantially equivalent predicate device with this specific indication did not exist and did not give clearance to market the pain pumps for use in the

joint space. Young Decl. Exs. 5, 6 (Petty Dep. at 43-44), 10 (Petty Dep. at 199). Warner maintains that Stryker nonetheless continued to market and sell its pain pump for use directly in the joint space, in violation of FDA regulations. Stryker denies these allegations.

On July 15, 2004, Warner underwent arthroscopic surgery on his shoulder, and his surgeon used a Stryker pain pump device to administer local anesthetics for up to seventy-two hours following surgery. Warner's surgeon, Dr. Benz, placed the pain pump catheter directly into Warner's shoulder joint to deliver the prescribed pain medication. Warner later developed glenohumeral chondrolysis, a rare and painful condition involving the rapid and permanent destruction of articular cartilage in the shoulder joint.

On November 13, 2008, Warner filed suit. Warner maintains that Stryker was on notice that the use of pain pumps to deliver pain medication directly to the shoulder joint could cause harm, and that Stryker nonetheless marketed its pain pumps for such use and failed to warn physicians that pain pumps had not been cleared for such use by the FDA.

DISCUSSION

Stryker moves for summary judgment on grounds that Warner fails to present any evidence that, at the time of his surgery, the scientific or medical community had reason to know of risks associated with using pain pumps to administer local anesthetics

directly to the joint space. Stryker emphasizes that under Oregon law, a manufacturer's duty to warn is limited to the dangers of which it knew or reasonably should have known. See McEwen v. Ortho. Pharm. Corp., 270 Or. 375, 385-86, 528 P.2d 522 (1974) (drug manufacturer has duty "of making timely and adequate warnings to the medical profession of any dangerous side effects produced by its drugs of which it knows, or has reason to know"). Thus, Stryker maintains that because it did not know or have reason to know of any association between pain pump use and chondrolysis as of July 2004, Warner cannot prevail on his products liability or negligence claims.[1] I disagree and find that genuine issues of material fact preclude summary judgment.

Though not overwhelming, Warner presents some evidence that Stryker knew or should have known of toxicity concerns associated with the administration of local anesthetics directly into the joint area. Warner submits the declaration of an orthopedic surgeon who asserts that prior to 2000, existing medical and scientific knowledge indicated that "continuous exposure to foreign solutions could be harmful" to articular cartilage and would have put a medical device manufacture on notice that the continuous

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[1]Warner's counsel maintains that a strict products liability claim based on failure to warn does not require that the manufacturer knew or should have known of the alleged risk of harm but only that the device was unreasonably dangerous without an adequate warning. Given that I find questions of fact regarding Stryker's actual or constructive knowledge, I need not address this issue.

infusion of anesthetics for one to two days "would likely risk injury to the cartilage." Trippel Decl. Ex. A at 5-13 (citing attached articles). Warner also presents internal documents of Stryker discussing the lack of FDA clearance or approval for "inter-articular injection" of a certain pain medication and referencing anesthetic "toxicity" concerns associated with pain pump use. Young Decl. Exs. 13, 62-63 (filed under seal). Stryker maintains that these documents are not relevant because no competent evidence establishes that the toxicity referred to was chondrotoxicity and objects to the consideration of such evidence on this and hearsay grounds. Stryker's Reply to Pl.'s Statement of Material Facts at 16. I overrule Stryker's objection and find the documents relevant. The type of toxicity to which the documents refer is a factual finding not appropriate for this court to make on summary judgment, and the documents are submitted to establish notice.

Finally, Warner's evidence must be considered in the context of Stryker's regulatory and marketing efforts and the lack of a specific indication for the use of pain pumps in the joint space, the FDA's determination that no predicate device established the efficacy and safety of such use, and Stryker's continued promotion of the pain pumps for use in the joint space without a specific indication cleared by the FDA. David Decl. Ex. A at 5-6; Young Decl. Exs. 20, 64 (filed under seal). Construing all inferences in

favor of Warner, he presents sufficient evidence to create a genuine issue of material fact as to whether Stryker should have known or anticipated that the administration of local anesthetics directly into the shoulder joint was toxic or otherwise harmful. Monroe v. Zimmer U.S. Inc., 766 F. Supp. 2d 1012, 1036-38 (E.D. Cal. 2011); Hackett v. Breg, Inc., 2011 WL 4550186, at *2-3 (D. Colo. Oct. 03, 2011); Hamilton v. Breg, Inc., 2011 WL 780541, at *3-5 (D. Ohio Jan. 20, 2011); Koch v. Breg, Inc., 2010 WL 5301047, at *2-4 (D.S.D. Dec. 20, 2010). It is not incumbent on Warner to show that Stryker should have known of the specific injury or damage - chondrolysis - allegedly caused by the use of the pain pumps.

I recognize that several courts have held otherwise and found that any danger from intra-articular pain pump use was "not knowable" prior to 2005 or 2006. Rodriguez v. Stryker Corp., 2011 WL 31462, at *8 (M.D. Tenn. Jan. 05, 2011); see also Krumpelbeck v. Breg, Inc., 759 F. Supp. 2d 958, 974 (S.D. Ohio 2010); Pavelko v. Breg, Inc., 2011 WL 782664, at *5-6 (D. Colo. Feb. 28, 2011); Phillippi v. Stryker Corp., 2010 WL 2650596, at *2-3 (E.D. Cal. July 1, 2010); Meharg v. I-Flow Corp., 2010 WL 711317, at *3-4 (S.D. Ind. Mar. 1, 2010). I respectfully disagree with those decisions and instead find this question appropriate for the trier of fact. It may well be that Warner's evidence at trial will fail to show by a preponderance that Stryker had reason to know of the

risks associated with intra-articular pain pump use. As noted by one district judge, "[t]he medical evidence that pain pumps could cause chondrolysis was at best fragmentary at the time" of Warner's surgery. Hamilton, 2011 WL 780541, at *3. On a motion for summary judgment, however, all inferences must be construed in favor of Warner. So construed, genuine issues of material fact remain.

Stryker also contends that Warner cannot show any alleged failure to warn by Stryker caused Warner's injury. Vaughn v. G.D. Searle & Co., 272 Or. 367, 369, 536 P.2d 1247 (1975). Stryker emphasizes Dr. Benz's deposition testimony stating that he did not read the Instructions for Use accompanying the Stryker pain pump prior to Warner's surgery or rely on statements from Stryker's sales representatives, placing into question whether Stryker's alleged failure to warn could have caused Warner's injury. Horwitz Decl. Ex. W. However, Dr. Benz's testimony must be considered in the context of Stryker's marketing strategies, along with his sworn testimony that he would not have used pain pumps to administer anesthetics directly to the joint space if he had known the FDA had not cleared the pain pumps for such use. Young Decl. Ex. 74. Although Stryker objects to Dr. Benz's statement as "speculative," given the circumstances as a whole, I do not find it so speculative as to warrant its exclusion.

Finally, Stryker moves for summary judgment regarding Warner's prayer for punitive damages. As with other pain pump cases, Warner

here presents little evidence that Stryker had actual knowledge of the risk of harm allegedly caused by pain pumps at the time of Warner's surgery, such that Stryker acted with "malice" or a "reckless and outrageous indifference to a highly unreasonable risk of harm" and with "conscious indifference to the health, safety and welfare of others" by marketing its pain pumps for intra-articular uses. Or. Rev. Stat. § 31.730(1); Andor v. United Air Lines, Inc., 303 Or. 505, 517, 739 P.2d 18 (1987) (punitive damages "are a penalty for conduct that is culpable by reason of motive, intent, or extraordinary disregard of or indifference to known or highly probable risks to others"). However, as explained above, the extent of Stryker's knowledge is a question of fact, and I decline to grant summary judgment at this time.

CONCLUSION

Stryker's Motion for Summary Judgment (doc. 127) is DENIED.

IT IS SO ORDERED.

DATED this 28th day of November, 2011.

Ann Aiken
United States District Judge